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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,685	05/04/2005	Giampiero De Luca	263388US0PCT	9272
22850	7590	03/12/2009		
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER ZAREK, PAUL E	
			ART UNIT	PAPER NUMBER
			1617	
			NOTIFICATION DATE	DELIVERY MODE
			03/12/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/519,685	Applicant(s) DE LUCA, GIAMPIERO	
	Examiner Paul Zarek	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Status of the Claims

1. Claims 1-24 have been amended and Claims 25-27 have been added by the Applicant in correspondence filed on 03/31/2005. Claims 1-27 are currently pending.

Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-14, drawn to a method of improving the fertilization activity of spermatozoa comprising treating spermatozoa with a compound of formula (I) wherein X is -S- or -O-, and Cy is a 6 membered aryl group, which may be fused to an additional aryl, heteroaryl, cycloalkyl, or heterocycloalkyl group.

Group II, claim(s) 1, 13, and 14, drawn to a method of improving the fertilization activity of spermatozoa comprising treating spermatozoa with a compound of formula (I) wherein formula (I) is not encompassed by Group I.

Group III, claim(s) 15, drawn to spermatozoa obtained by the process of Group I.

Group IV, claim(s) 15, drawn to spermatozoa obtained by the process of Group II.

Group V, claim(s) 16, 17, 20, and 21, drawn to a method of improving fertilization comprising utilization of formula (I) wherein X is -S- or -O-, and Cy is a 6 membered aryl group, which may be fused to an additional aryl, heteroaryl, cycloalkyl, or heterocycloalkyl group.

Group VI, claim(s) 16, 17, 20, and 21, drawn to a method of improving fertilization comprising utilization of formula (I) wherein formula (I) is not encompassed by Group V.

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Group VII, claim(s) 18, 19, 25, and 26, drawn to a method of making a pharmaceutical composition comprising the addition of formula (I) wherein X is -S- or -O-, and Cy is a 6 membered aryl group, which may be fused to an additional aryl, heteroaryl, cycloalkyl, or heterocycloalkyl group to a pharmaceutical composition.

Group VIII, claim(s) 18, 19, 25, and 26, drawn to a method of making a pharmaceutical composition comprising the addition of formula (I) wherein formula (I) is not encompassed by Group VII to a pharmaceutical composition.

Group IX, claim(s) 22-24 and 27, drawn to a medium for the storage and/or transportation of spermatozoa comprising a compound of formula (I) wherein X is -S- or -O-, and Cy is a 6 membered aryl group, which may be fused to an additional aryl, heteroaryl, cycloalkyl, or heterocycloalkyl group.

Group X, claim(s) 22-24 and 27, drawn to a medium for the storage and/or transportation of spermatozoa comprising a compound of formula (I) wherein formula (I) is not encompassed by Group IX.

3. The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Luconi, et al. (International Application No. WO 01/07021, provided in IDS) teach a medium for the storage and/or transportation of spermatozoa comprising a drug (Claim 21). Although Luconi, et al., do not disclose formula (I), one of ordinary skill in the art would readily recognize that the disclosed PI3K inhibitor could be substituted with formula (I) of the instant application. Thus, the instant application lacks inventive step and, hence, a special technical feature.

Election of Species

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

a compound of formula (I) wherein the identity and location of Cy, X, Y¹, Y², A, R¹, R², Z, G, W, V, n, m, o, and q (where applicable) are specified

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Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

5. The claims are deemed to correspond to the species listed above in the following manner:

Group I: Claims 2-12; and,
Group II-X: none.

The following claim(s) are generic:

Groups I and II: Claims 1, 13, and 14;
Groups III and IV: Claim 15;
Groups V and VI: Claims 16, 17, 20, and 21;
Groups VII and VIII: Claims 18, 19, 25, and 26; and,
Groups IX and X: Claims 22-24 and 27.

6. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Luconi, et al. (International Application No. WO 01/07021, provided in IDS) teach a medium for the storage and/or transportation of spermatozoa comprising a drug (Claim 21). Although Luconi, et al., do not disclose formula (I), one of ordinary skill in the art would readily recognize that the disclosed PI3K inhibitor could be substituted with formula (I) of the instant application. Thus, the instant application lacks inventive step and, hence, a special technical feature.

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7. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be

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amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Zarek whose telephone number is (571) 270-5754. The examiner can normally be reached on Monday-Thursday, 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PEZ

/Rita J. Desai/
Primary Examiner, Art Unit 1625